

Université **m** de Montréal

ANNOUNCEMENT

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A WORLD FIRST IN PEDIATRIC CANCERS AT SAINTE-JUSTINE

CLINICAL STUDY LAUNCHED IN PATIENTS FACING A THERAPEUTIC DEAD END

MONTRÉAL, September 1st, 2015 – The CHU Sainte-Justine Research Centre is initiating its first clinical study in pediatric cancer and the first DEC-GEN study to be conducted in the world in children with solid tumors or recurrent or refractory leukemia. Designed at the CHU Sainte-Justine by principal investigators Noël Raynal and Henrique Bittencourt –both professors at Université de Montréal–, the DEC-GEN study aims to evaluate the effectiveness, in children, of a combination of drugs which are already used individually in the treatment of cancers. This drug combination therapy gives hope for survival, healing and improved quality of life to the 20% of children who do not respond to standard treatments.

The innovative approach of the DEC-GEN study lies in the epigenetic action created by combining two drugs, namely decitabine, used to treat acute leukemias, and genistein, a natural isoflavone found in soybeans. The two molecules act synergistically to reprogram cancer cells and stop their progression, specifically targeting epigenetic alterations such as DNA hypermethylation, responsible for repressing tumor suppressor genes.

"The DEC-GEN combination is significantly less toxic than conventional therapies, because the effective dose is minimized through the synergetic action of the two molecules," says Noël Raynal, drawing upon the preliminary results of a clinical trial that was conducted among patients with solid tumors at the Notre-Dame Hospital of the CHUM, on behalf of the INRS – Institut Armand Frappier (INRS-IAF).

Phase I of the study will be conducted in the first year at CHU Sainte Justine in some 12 patients aged 2 to 20 years facing a therapeutic dead end, in order to assess the impact of a dose-escalated treatment on biological factors – including DNA methylation, as well as on pharmacokinetic and pharmacogenetic parameters. Once the optimal dose is identified, phase II of the study will be extended to other pediatric oncology centers in Canada. In total, we aim to treat 24 patients in the course of this study.

In addition to achieving the obvious sought and expected clinical benefits for patients, the researchers are confident that their work will broaden the horizon of scientists in their quest for other combinations of epigenetic drugs to fight cancers.

About the researchers

<u>Dr. Noël Raynal</u>, is a researcher at CHU Sainte-Justine and assistant professor in the Department of Pharmacology at Université de Montréal. <u>Dr. Henrique Bittencourt</u> is a hemato-oncologist and a researcher at CHU Sainte-Justine, and an assistant clinical professor in the Department of Pediatrics at Université de Montréal.

About the study

The DEC-GEN study is carried in collaboration with INRS-IAF. It has been made possible thanks to the financial support of Gateway for Cancer Research and the in kind contribution of Pharmascience and DSM Nutritional Products, who respectively will be providing decitabine and genistein at no charge for the duration of the study. People interested in the study may contact the research team to learn more.

Information

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About the CHU Sainte-Justine Research Center

CHU Sainte-Justine Research Center is a leading mother-child research institution affiliated with the Université de Montréal. It brings together more than 200 research investigators, including over 90 clinicians, as well as 350 graduate and post-graduate students focused on finding innovative prevention means, faster and less invasive treatments, as well as personalized approaches to medicine. The Center is part of CHU Sainte-Justine, which is the largest mother-child center in Canada and second most important pediatric center in North America. More on research.chusj.org

Source

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